REMARKS

Claims 1-18 were pending. In the Office Action mailed August 25, 2004, the Examiner summarily withdrew claims 9, and 11-18 as allegedly drawn to non-elected inventions. Without acquiescing to the Examiner's allegation that claims 9, and 11-18 are drawn to non-elected inventions, while expressly reserving the right to prosecute these withdrawn claims (or claims similar thereto) in subsequent application(s), the Applicant (in order to advance business interests) acknowledges the pending claims, in the instant prosecution, are claims 1-8 and 10.

The Examiner made the following objections and rejections.

(1) The Examiner requests the specification be amended to recite the priority claim recited in the transmittal papers of the application as filed.
(2) The Examiner requests the submission of an Abstract.
(3) The Examiner requests redaction of embedded hyperlinks in the specification.
(4) The Examiner rejects claims 1-8 and 10 under 35 U.S.C. §112 (first paragraph).
(5) The Examiner rejects claims 1, 6, and 8 under 35 U.S.C. §102(b)[1].

The Applicant's remarks are presented in the same order as the objections and rejections set out above.

1 – 3. The Applicant Corrects Informalities

The Applicant has: i) amended the specification to recite a priority claim to a previously filed provisional application, ii) entered an Abstract, and iii) redacted all embedded hyperlinks in the specification. The Applicant, therefore, has corrected the informalities cited by the Examiner in the Office Action mailed August 25, 2004. In addition, the Applicant has amended numerous paragraphs from the specification to: i) correct formatting irregularities, ii) amend nomenclature and, iii) to insert SEQ ID NOs.

[1] The Examiner also rejects claim 59 but given this claim was never in the instant prosecution, the Applicant presumes the inclusion of the same in the rejected claim set, was a clerical oversight.

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4. The Claims Are Enabled

A. The Examiner Fails To Make A *Prima Facie* Case.

The Examiner rejects claims 1-8 and 10 under 35 U.S.C. 112, first paragraph. Specifically, the Examiner alleges the Specification contains "subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the claimed invention."[2] The Examiner is reminded that, "it is incumbent upon the Patent Office, whenever a rejection on [the basis of lack of enablement] is made, to explain why it doubts the truth or accuracy of any statement in supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971).

In view of *In re Marzocchi*, the Examiner fails to provide adequate explanation, evidence, or reasoning as to why the Applicant's Specification fails to enable the scope of the invention as claimed. Instead, the Examiner summarily applies an "undue experimentation" stamp upon the case (without consideration of the adequacy of the specific teachings in the Application as filed) to improperly advance a *prima facie* case.

B. The Specification Enables The Claims As Filed

The Examiner asserts the, "specification provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the claimed universal vaccine would function as claimed or as contemplated with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention."[3] The Examiner is reminded that, in an undue experimentation analysis, "[t]he key word is 'undue' not 'experimentation.'" *In re Angstadt and Griffin*, 190 USPQ 214, 219 (CCPA 1976). Indeed, "a considerable amount of experimentation is permissible . . . if the specification in question provides a reasonable amount of guidance with respect to the direction in which the

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[2] *See*, Office Action mailed August 25, 2004, page 3, number 7.

[3] *Id.* at page 9, lines 22-25 and page 10, lines 1-2.

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experimentation should proceed . . . ." *Ex parte Jackson*, 217 USPQ 804, 807 (Bd. App. 1982); *In re Wands*, 8 USPQ 2d 1400, 1404 (CAFC 1988). MPEP 2164.01 (a).

The Examiner's case for undue experimentation, therefore, needs be based on an evaluation of Applicant's teaching and is not satisfied by the Examiner's personal speculation about hypothetical "problems" associated with vaccine development or citation to alleged technical problems encountered by others in published references.

That is to say, the Examiner's observations that, "[it] cannot be predicted from the information in the specification as to whether or not the claimed vaccine is either safe or possible to use as contemplated." and that "one cannot extrapolate the teaching of the prediction to the enablement of the claims because neither the *in vitro* nor the *in vivo* studies presented in the specification are commensurate in scope with the claimed invention which is drawn to a '. . . universal vaccine for the treatment of cancer.'"[4] are of no moment.

Significant, however, is the Examiner's admission that the specification is enabling for, "a universal vaccine for treating tumors of any origin comprising SEQ ID NOS: 1 and 2, wherein the patients treated express HLA-A2.1,. . .".[5] In view of well settled case law that stands for the proposition that, "[a]s long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied"; the Applicant respectfully submits the Examiner's admission, highlighted above, is the best rebuttal to the pending rejection under 35 U.S.C. § 112 (first paragraph) . See, *In re* Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Moreover, the Applicant's presentation (in the specification) of both a functional assay and structural motifs; provide a teaching sufficient to allow for the synthesis of any TRT peptide that is capable of initiating and/or enhancing a CTL response restricted by a given MHC receptor (*e.g.*, HLA-A2 and HLA-Aw69 molecules recognized by the BB7.2 monoclonal antibody).[6]

However without acquiescing to any of the Examiner's arguments, while expressly reserving the right to prosecute the claims as originally filed (or claims similar thereto), the

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[4] *Id.*at page 5, lines 23-25 and page 6 line 1.
[5] Id., page 10, lines 3–7.
[6] *See, for example*, published specification in paragraphs [0031], [0033], and [0046], and in Tables II, III and IV (in particular footnote b of Table II).

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Applicant has amended, in part, the only pending independent claim (i.e. claim 1) by deleting the word "universal". The pending independent claim now recites a vaccine for treating tumors of any origin, comprising: at least one telomerase reverse transcriptase (TRT) peptide in an amount effective for initiating and enhancing a cytotoxic T lymphocyte (CTL) response against mammalian cancer cell a physiologically acceptable carrier; and a helper peptide. The Applicant respectfully submits that, for the reason discussed above, the scope of the pending claims are enabled by the Specification and, therefore, all the pending claims satisfy 35 U.S.C. § 112 (first paragraph).

In addition, the Applicant has added new Claims 19-24, directed to compositions for induction of a cytotoxic T lymphocyte response "comprising: at least one HLA-A2-restricted telomerase reverse transcriptase (TRT) peptide in an amount effective for initiating and enhancing a cytotoxic T lymphocyte (CTL) response against an HLA-A2 positive target cell; and a physiologically acceptable carrier." Support for the new claims is found for instance in the text of the original claims, as well as in Example 11 and Tables II and III, which describe the lysis of various HLA-A2 expressing target cells, and provide the sequence of various HLA-A2 restricted TRT peptides, respectively.

5. The Claims Are Not Anticipated

In order to further business interests, and without acquiescing to the Examiner's arguments (while expressly reserving the right to prosecute the claims as filed or claims similar thereto) the Applicant has, in part, amended the only pending independent claim (i.e. claim 1) to incorporate the element of "a helper peptide." This amendment adds no new matter as the specification teaches, in selected embodiments, the inclusion of a "helper peptide"[7] in the invention as presently claimed.

The Applicant respectfully submits that U.S. patent 6,093,809 is silent on:

> a vaccine for treating tumors of any origin, comprising: at least one telomerase reverse transcriptase (TRT) peptide in an amount effective for initiating and enhancing a cytotoxic T lymphocyte (CTL) response against mammalian cancer cells; a physiologically acceptable carrier; and a helper peptide.

[7] *See*, published specification in paragraphs [0057], [0074] and TABLE II.

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Therefore, this reference (as cited in the Office Action mailed August 25, 2005) fails to disclose each and every element of the selected embodiments of the invention as presently claimed. Given that a single reference must disclose each limitation of a claim, in order for that reference to anticipate the claim, the Applicant submits the '809 patent cannot sustain a rejection under 35 U.S.C. §102(b). See, *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984). The Applicant, therefore, respectfully requests the pending rejection under 35 U.S.C. §102(b) be withdrawn.

In addition, new Claims 19-24 include the limitation of a "at least one HLA-A2-restricted telomerase reverse transcriptase (TRT) peptide." In contrast, the '809 Patent does not provide any teaching regarding HLA-restriction of telomerase peptides. Thus, the new claims are also not anticipated by the '809 Patent.

CONCLUSION

The Applicant believes the arguments set forth above traverse the Examiner's rejections and therefore request these grounds for rejection be withdrawn. Should the Examiner believe a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect.

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